Complete Summary

GUIDELINE TITLE

HIV prophylaxis following non-occupational exposure including sexual assault.

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. HIV prophylaxis following non-occupational exposure including sexual assault. New York (NY): New York State Department of Health; 2004. 42 p. [30 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Human immunodeficiency virus (HIV) infection

Hepatitis B virus (HBV) infection

Hepatitis C virus (HCV) infection

GUIDELINE CATEGORY

Counseling
Evaluation
Management
Prevention

Risk Assessment
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Emergency Medicine
Family Practice
Infectious Diseases
Obstetrics and Gynecology
Psychology

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Public Health Departments
Social Workers
Substance Use Disorders Treatment Providers

GUIDELINE OBJECTIVE(S)

To provide recommendations and guidelines for prescribing post-exposure prophylaxis (PEP) following non-occupational exposure to human immunodeficiency virus (HIV), including significant risk exposures following sexual and needle-sharing activities, needlesticks outside of occupational settings, trauma, human bites, and sexual assault

TARGET POPULATION

Adults who have (or have potentially) been exposed to human immunodeficiency virus (HIV) via sexual or needle-sharing activities, needlesticks outside of occupational settings, trauma, human bites, and sexual assault

INTERVENTIONS AND PRACTICES CONSIDERED

1. Post-exposure prophylaxis following non-occupational exposures (nPEP)
    - Assessment to determine whether nPEP is indicated
    - Baseline testing for patients who present with risk exposures
        - Human immunodeficiency virus (HIV) testing
        - Sexually transmitted disease (STD) testing
        - Pregnancy testing
    - Recommending nPEP
    - Behavioral intervention and risk-reduction counseling
2. PEP For Sexual Assault Survivors
    - Assessment to determine whether nPEP is indicated following sexual assault
    - Recommending nPEP for sexual assault survivors

- Coordination of care with rape crisis counselors and sexual assault forensic examiners (SAFEs)
- HIV testing of the survivor

3. PEP medications
    - Recommended regimen: Zidovudine (ZDV) (Retrovir) + Lamivudine (3TC) (Epivir) + Tenofovir (TDF) (Viread)
    - Alternative antiretroviral medications (not recommended as first line therapy):
        - Nucleoside reverse transcriptase inhibitor (NRTI): stavudine (d4T) (Zerit)
        - Non-nucleoside reverse transcriptase inhibitors (NNRTIs): efavirenz (EFV) (Sustiva), nevirapine* (NVP) (Viramune)
        - Protease inhibitors: indinavir (IDV) (Crixivan), lopinavir/ritonavir (LPV/r) (Kaletra), nelfinavir (NFV) (Viracept)

*Note from the National Guideline Clearinghouse: On January 19, 2005, the U.S. Food and Drug Administration (FDA) issued a public health advisory about recent safety-related changes to the nevirapine (Viramune®) label and about appropriate use of HIV triple combination therapy containing nevirapine. The Indications and Usage section now recommends against starting nevirapine treatment in women with CD4+cell counts greater than 250 cells/mm^3 unless benefits clearly outweigh risks. This recommendation is based on a higher observed risk of serious liver toxicity in patients with higher CD4 cell counts prior to initiation of therapy. See the FDA Web site for more information.

4. Monitoring following non-occupational exposure including sexual assault
5. Non-occupational PEP for the pregnant patient
6. Non-occupational PEP for hepatitis B virus (HBV) and hepatitis C virus (HCV)

MAJOR OUTCOMES CONSIDERED

- Human immunodeficiency virus (HIV) transmission rate after exposure to HIV and after prophylaxis
- Seroconversion
- Vertical transmission
- Cost, side effects, and toxicity of post-exposure prophylaxis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Human Immunodeficiency Virus (HIV) Guidelines Program works directly with committees composed of HIV Specialists to develop clinical practice guidelines. These specialists represent different disciplines associated with HIV care, including infectious diseases, family medicine, obstetrics and gynecology, among others. Generally, committees meet in person three to four times per year, and otherwise conduct business through monthly conference calls.

Committees meet to determine priorities of content, review literature, and weigh evidence for a given topic. These discussions are followed by careful deliberation to craft recommendations that can guide HIV primary care practitioners in the delivery of HIV care. Decision making occurs by consensus. When sufficient evidence is unavailable to support a specific recommendation that addresses an important component of HIV care, the group relies on their collective best practice experience to develop the final statement. The text is then drafted by one member, reviewed and modified by the committee, edited by medical writers, and then submitted for peer review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Cost-effectiveness analyses have suggested that non-occupational post-exposure prophylaxis (nPEP) is cost-effective in high-risk exposures such as receptive anal sex with a human immunodeficiency virus (HIV)-infected partner or a partner of unknown HIV status.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Key Points

- Non-occupational post-exposure prophylaxis (PEP) should never replace adopting and maintaining preventive behaviors and is not routinely recommended in situations in which high-risk behavior is habitually practiced.
- Risk-reduction counseling is a major and essential complement to PEP.

Post-Exposure Prophylaxis Following Non-Occupational Exposures (nPEP)

Assessment to Determine Whether nPEP Is Indicated

- Whenever possible, risk assessment and initiation of nPEP should occur in clinical settings where human immunodeficiency virus (HIV) prevention counseling services, as well as HIV clinical expertise, are available or are easily accessed by referral.
- Patients who present for nPEP should be evaluated as soon as possible in order to initiate therapy, if indicated, within recommended time frames (see "Timing of Initiation of PEP for all Non-Occupational Exposures" below).
- When deciding whether to recommend the initiation of nPEP, the clinician should assess and carefully weigh the following factors (see Table 1 in the original guideline document):
    - the behavioral factors and circumstances that led to HIV exposure
    - the patient's risk of HIV acquisition based on the type of exposure
    - the possibility that the source is HIV-infected
- The clinician should provide risk-reduction counseling and primary prevention counseling whenever someone is assessed for nPEP, regardless of whether PEP is initiated.
- Non-occupational PEP should not be prescribed when there is negligible or low risk of HIV transmission (see Table 2 in the original guideline document).
- Non-occupational PEP should not be used as a pre-exposure prophylactic measure to prevent HIV transmission in a woman wishing to become pregnant with an HIV infected male partner, or as prophylaxis for any person who plans to engage in high risk behavior.

- Clinicians should provide supportive counseling and make referrals for counseling for patients for whom nPEP is not prescribed.

Baseline Testing for Patients Who Present With Risk Exposures

- The clinician should perform baseline HIV testing of the exposed person. Initiation of nPEP should not be delayed pending HIV test results. Where available, rapid testing should be used.
- The clinician should perform an assessment for other sexually transmitted diseases (STDs), such as chlamydia, gonorrhea, and syphilis, and should provide STD prophylaxis in sexually exposed patients.
- The clinician should obtain baseline pregnancy testing for exposed women. Emergency contraception should be offered to and discussed with women at risk of pregnancy from the exposure.

Deciding To Recommend nPEP

- The clinician should initiate nPEP ideally within two hours and no later than thirty-six hours following exposure when an isolated exposure (sexual, needle, or trauma) has occurred, when risk-reduction practices fail, or in the instance of regretted exposure.
- The clinician should discuss the following issues with the patient and should document that they were discussed before initiating a regimen:
    1. The potential benefit, unproven efficacy, and potential toxicity of nPEP
    2. The need for adherence
    3. The need to initiate/resume risk-reduction and preventive behaviors
    4. Signs and symptoms of primary HIV infection
    5. The need for clinical and laboratory monitoring and follow-up
- The patient should agree to follow-up monitoring and initiation of interventions to reduce risk, if applicable, before the clinician initiates nPEP. All components of this discussion should be documented so that events leading to infection can be clearly identified and the efficacy of nPEP can be assessed.

Behavioral Intervention and Risk-Reduction Counseling

- Behavioral intervention for risk reduction should occur regardless of whether nPEP is initiated or not.
- Clinicians should assess for emotional, psychological, and social factors that can contribute to risk behavior, such as depression, history of sexual abuse, and drug and alcohol use.
- Clinicians should refer patients to mental health and/or substance use programs when indicated and should consider the need for intensive risk-reduction counseling services.

<u>PEP For Sexual Assault Survivors</u>

- Survivors of sexual assault should be treated in an emergency department or equivalent healthcare setting where all appropriate medical resources are available as needed.

Assessment To Determine Whether nPEP Is Indicated Following Sexual Assault

- When deciding whether to recommend the initiation of nPEP to the survivor, the clinician should assess and carefully weigh the following factors:
    - Whether or not a significant exposure has occurred during the assault
    - Knowledge of the HIV status of the alleged assailant
    - Whether the survivor is ready and willing to complete the nPEP regimen
- The clinician's decision to recommend nPEP should not be influenced by the geographic location of the assault.

Degree Of Risk Based On Type Of Exposure

- Clinicians should recommend HIV nPEP to survivors when significant exposure may have occurred, as defined by direct contact of the vagina, anus, or mouth with the semen or blood of the alleged assailant, with or without physical injury, tissue damage, or presence of blood at the site of the assault.
- Non-occupational PEP should also be offered in cases of assault or trauma involving broken skin or when mucous membranes of the survivor have been in contact with blood or semen of the alleged assailant. Similarly, nPEP should be offered in cases of bites that result in visible blood.

Considering the HIV Status Of The Alleged Assailant

- Unless the identity and HIV status of the alleged assailant has been clearly established to assist with the decision-making, nPEP should be promptly initiated when a significant risk exposure has occurred.
- Even when the alleged assailant is known to be HIV infected, the decision to recommend nPEP should be based on the nature of the exposure and the survivor's ability to complete the regimen.
- If prophylaxis has been initiated and the alleged assailant is found to be HIV antibody negative, then nPEP should be discontinued.

Recommending nPEP For Sexual Assault Survivors

- Non-occupational PEP should be initiated as soon as possible after exposure. Non-occupational PEP is unlikely to be effective more than 36 hours post-exposure. (See "Timing of Initiation of PEP for All Non-Occupational Exposures" below.)
- Starter packs of medication should be available on-site for rapid initiation of nPEP following sexual assault. Arrangements should be made to ensure that the patient receives a continued supply of medication and is referred to an HIV specialist.
- The recommendation for nPEP should be communicated simply and clearly to the patient, considering his/her emotional state and ability to comprehend the nature of antiretroviral (ARV) treatment.
- If a sexual assault survivor is too distraught to engage in a discussion about the drug regimen or make a decision about whether to initiate treatment at the initial assessment, the clinician should offer a first dose of medication and make arrangements for a follow-up appointment within twenty-four hours to further discuss the indications for nPEP.

- If a sexual assault survivor decides to initiate treatment, a follow-up visit should be scheduled within twenty-four hours to review the decision, evaluate initial drug tolerability, reinforce the need for adherence to the regimen, and arrange for follow-up care.
- The discussion regarding initiation of nPEP should include the following:
    - The potential to prevent HIV infection
    - Possible side effects of the nPEP regimen
    - Duration of nPEP and the monitoring schedule
    - Importance of adherence to the treatment regimen to prevent nPEP failure or the development of drug resistance should infection occur

The Role of the Rape Crisis Counselor And Sexual Assault Forensic Examiner

- The rape crisis counselor should be an active participant in the discussion regarding HIV nPEP.
- The plan for follow-up care should be discussed with the rape crisis counselor or an outreach worker who will be working with the survivor following the survivor's departure from the emergency department or equivalent healthcare setting.

Key Point:

- The rape crisis counselor may play a pivotal role in helping the survivor better understand the potential benefits of prophylaxis and its side effects, the complex dosing schedule, and the importance of treatment adherence.

HIV Testing Of The Survivor

- Clinicians should obtain blood for baseline HIV serologic testing when recommending initiation of nPEP. Prophylaxis, when indicated, should be started without waiting for the results of this test.
- Refusal to undergo baseline testing should not preclude initiation of nPEP.

Key Point:

- Use of rapid HIV testing technology in the setting of sexual assault should balance the potential benefit of avoiding unnecessary initiation of PEP (for a patient who has existing, undiagnosed HIV infection) against the potential harm to the emotional state of the survivor from learning of a positive test result in the immediate aftermath of having been assaulted.

Timing Of Initiation Of PEP For All Non-Occupational Exposures

- Non-occupational PEP should be offered as soon as possible after exposure and initiated ideally within two hours and no later than 36 hours following exposure. Non-occupational PEP is unlikely to be effective more than 36 hours post-exposure.

Recommended nPEP Regimens (please refer to the original guideline document for more information)

- Clinicians should initiate three-drug ARV therapy for significant exposures to HIV. The preferred nPEP regimen is zidovudine 300 milligrams by mouth twice per day + lamivudine 150 milligrams by mouth twice per day (or co-formulated as Combivir one tablet twice per day) plus tenofovir 300 milligrams by mouth daily. Alternative agents may be used in the setting of drug intolerance or toxicity (see Table 5 and Appendix A in the original guideline document).
- When the patient is known to be HIV infected and information regarding previous ARV therapy, current level of viral suppression, or genotypic/phenotypic resistance profile is available, the clinician, in consultation with an HIV Specialist, should individualize the regimen to more effectively suppress viral replication.
- The nPEP regimen should be continued for four weeks.

HIV PEP Regimen Following Non-Occupational Exposure*†

- Zidovudine‡ 300 mg by mouth twice per day + Lamivudine 150 mg by mouth twice per day (or Combivir 1 table twice a day)§ plus Tenofovir 300 mg by mouth daily¶
    - Non-nucleoside reverse transcriptase inhibitors (NNRTIs) should be considered only when:
        1. The patient cannot tolerate either tenofovir or a protease inhibitor alternative, or
        2. The patient has been exposed to a source with known drug-resistant HIV that is sensitive to NNRTIs.

* When the source is known to be HIV infected, past and current ARV therapy experience, viral load data, and genotypic or phenotypic resistance data (if available) may indicate the use of an alternative PEP regimen. Consult an HIV Specialist.

† NNRTIs should be considered only when 1) the patient cannot tolerate either tenofovir or a protease inhibitor alternative, or 2) the patient has been exposed to a source with known drug-resistant HIV that is sensitive to NNRTIs. Use of efavirenz should only be considered in men and in women not capable of bearing children because of associations with teratogenicity in animal studies and in anecdotal reports in humans. Initial central nervous system toxicity, often seen with efavirenz, may affect one's ability to work. Nevirapine is not recommended for women with CD4 counts >250 cells/mm^3 or men with CD4 counts >400 cells/mm^3 and should only be used when NRTIs or PIs are not an option and no other hepatic risk (e.g., hepatitis) is present. If nevirapine is used, it is essential that the 14-day lead-in period be strictly followed. Serum liver enzymes should be obtained at baseline, at dose escalation, and 2 weeks after dose escalation.

‡ If the patient is intolerant to zidovudine, stavudine 40 mg by mouth twice a day may be substituted (if patient is <60 kg, 30 mg by mouth twice a day should be given). Dosing interval of zidovudine should be adjusted in patients with baseline creatinine clearance <15 mL/min (see Appendix A in the original guideline document for dosing recommendations).

§ The dosing interval of lamivudine should be adjusted in patients with baseline creatinine clearance <50 mL/min (see Appendix A in the original guideline document for dosing recommendations). Because Combivir is a fixed-dose combination that cannot be adjusted, zidovudine 300 mg twice daily should be combined with lamivudine (dose adjusted for creatinine clearance).

¶ The dosing interval of tenofovir should be adjusted in patients with baseline creatinine clearance <50 mL/min (see Appendix A in the original guideline document for dosing recommendations).

Monitoring Following Non-Occupational Exposure Including Sexual Assault

- Clinicians should closely monitor people receiving nPEP to detect ARV-induced toxicities.
- Because of the complexity and potential adverse effects of the nPEP regimens, longitudinal care of the exposed patient should be provided either directly by or in consultation with an HIV Specialist.
- Sequential confidential HIV testing should be obtained at baseline, one, three, and six months post-exposure even if nPEP is declined. In New York State, if the test result is positive, a Western blot assay must be performed to confirm the diagnosis of HIV infection.
- Any acute febrile illness post-exposure accompanied by one or more of the following -- rash, lymphadenopathy, myalgias, sore throat -- suggests the possibility of acute HIV seroconversion and requires urgent evaluation. If this constellation of complaints is encountered, consultation with an HIV specialist should be sought for optimal diagnostic testing and treatment options.

Non-occupational PEP For Pregnant Patients

- Before administering nPEP to a pregnant woman, the clinician should discuss the potential benefits and risks to her and to the fetus. Drugs to avoid during pregnancy are listed in Table 7 in the original guideline document.
- Based on increasing clinical experience with highly active anti-retroviral therapy (HAART), nPEP is indicated at any time during pregnancy when a significant exposure has occurred, despite possible risk to the woman and the fetus. Expert consultation should be sought. A decision about the initiation of nPEP should be made within 36 hours of exposure, which is the period for optimal prophylaxis.
- Clinicians should not prescribe efavirenz for pregnant women because it has been associated with teratogenicity in monkeys.
- Clinicians should not prescribe amprenavir in the second and third trimesters because it may induce fetal skeletal ossification.
- Clinicians should not prescribe the combination of didanosine and stavudine due to an increased risk of mitochondrial toxicity in pregnant women.
- For women who may have been exposed to HIV, breastfeeding should be avoided for 6 months after the exposure. Because HIV infection is most often diagnosed within 3 months of exposure, women who would prefer to breastfeed between 3 to 6 months following exposure should carefully discuss the risks and benefits with the clinician.

Non-occupational PEP For Hepatitis B Virus (HBV) And Hepatitis C Virus (HCV)

- The hepatitis B vaccine series should be initiated in non-HBV-immune patients who sustain a blood or body fluid exposure.
- Administration of prophylactic hepatitis B immune globulin (HBIG) and the initiation of the hepatitis B vaccine series are recommended when the non-HBV-immune patient is exposed to a source with acute or chronic HBV (see Table 8 in the original guideline document).
- If the source is known to be HCV-antibody positive or if the serostatus is unknown, baseline HCV serology and serum alanine aminotransferase (ALT)

should be obtained from the exposed patient and should be repeated at 4 to 6 months post-exposure.
- If the source is known to be HCV-antibody positive, an HCV antibody and qualitative HCV viral load (HCV ribonucleic acid [RNA] polymerase chain reaction [PCR]) should be obtained from the exposed patent 4 weeks after exposure.
- In the setting of an acute elevation of alanine aminotransferase (ALT) in the exposed patient in the first twenty-four weeks post-exposure, a qualitative HCV RNA PCR should be obtained.
- When HCV infection is identified, the exposed patient should be referred for medical management to a clinician with experience in treating HCV.

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for non-occupational post-exposure prophylaxis including sexual assault.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Because there are no randomized, placebo-controlled experimental clinical trials on which to definitively base recommendations, these guidelines are based on best practice evidence and constitute the considered opinion of the group of expert clinicians in the field of adult human immunodeficiency virus (HIV) medicine who comprise the Medical Care Criteria Committee.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Post-exposure prophylaxis following non-occupational exposures (nPEP) offers the possibility of preventing human immunodeficiency virus (HIV) transmission when possible exposure to HIV has occurred.

Subgroups Most Likely to Benefit:

- Persons who have sustained injuries with exposure to blood from a source known to be HIV-infected or at risk for HIV infection (including needlesticks, human bites, accidents)
- Persons who have been exposed to receptive anal intercourse, receptive vaginal intercourse, or needlesharing with an infected source

POTENTIAL HARMS

Note from NGC: The following harms summarize the content of the guideline for the recommended regimen. Please refer to Appendix A in the original guideline document for additional information on these and other alternative medications.

Side Effects Associated With Pharmacotherapy:

Zidovudine (ZDV) (Retrovir):

- Gastrointestinal intolerance, headache, insomnia, asthenia, lipoatrophy
- Bone marrow suppression: anemia, neutropenia, and less commonly, thrombocytopenia
- Lactic acidosis with hepatic steatosis is a rare but potentially life-threatening toxicity
- Prolonged zidovudine use has been associated with symptomatic myopathy.
- Food and Drug Administration (FDA) pregnancy category: C

Lamivudine (3TC) (Epivir):

- Minimal toxicity for adults
- Lactic acidosis with hepatic steatosis is a rare but potentially life-threatening toxicity
- Epivir tablets and oral solution (used to treat human immunodeficiency virus [HIV] infection) contain a higher dose of lamivudine than Epivir-hepatitis B virus (HBV) tablets and oral solution (used to treat chronic hepatitis B). Patients with HIV infection should receive only doses and formulations appropriate for treatment of HIV infection.
- FDA pregnancy category: C

Tenofovir (TDF) (Viread):

- Asthenia, headache, diarrhea, nausea, vomiting, flatulence
- Although there have been no cases of lactic acidosis reported with TDF use, lactic acidosis with hepatic steatosis is a rare but potentially life-threatening toxicity with the use of nucleoside reverse transcriptase inhibitors (NRTIs).
- Rare reports of renal insufficiency
- Viread has in vitro activity against HBV but is not indicated for the treatment of chronic hepatitis B virus (HBV) infection and the safety and efficacy of Viread have not been established in patients co-infected with HBV and HIV. Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with HBV and HIV and have discontinued Viread. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue Viread and are co-infected with HIV and HBV. If appropriate, initiation of anti-hepatitis B therapy may be warranted.
- FDA pregnancy category: B

Drug Interactions:

- Zidovudine (ZDV) (Retrovir): stavudine, zalcitabine, doxorubicin, ganciclovir, ribavirin
- Lamivudine (3TC) (Epivir): abacavir + tenofovir, emtricitabine, tenofovir + didanosine, zalcitabine
- Tenofovir (TDF) (Viread): atazanavir with or without ritonavir, lamivudine + abacavir, lamivudine + didanosine, didanosine, lopinavir/ritonavir, cidofovir, ganciclovir, valganciclovir

CONTRAINDICATIONS

CONTRAINDICATIONS

Note from NGC: The following contraindications summarize the content of the guideline for the recommended regimen. Please refer to the original guideline document for additional information on these and other alternative medications.

Important Drug Interactions (Drugs to Avoid):

- Zidovudine (ZDV) (Retrovir): stavudine, zalcitabine, doxorubicin
- Lamivudine (3TC) (Epivir): abacavir + tenofovir, emtricitabine, tenofovir + didanosine, zalcitabine
- Tenofovir (TDF) (Viread): atazanavir without ritonavir, lamivudine + abacavir, lamivudine + didanosine

Contraindicated In Pregnancy: efavirenz, amprenavir, stavudine + didanosine

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Following the development and dissemination of guidelines, the next crucial steps are adoption and implementation. Once practitioners become familiar with the content of guidelines, they can then consider how to change the ways in which they take care of their patients. This may involve changing systems that are part of the office or clinic in which they practice. Changes may be implemented rapidly, especially when clear outcomes have been demonstrated to result from the new practice such as prescribing new medication regimens. In other cases, such as diagnostic screening or oral health delivery, however, barriers emerge which prevent effective implementation. Strategies to promote implementation, such as through quality of care monitoring or dissemination of best practices, are listed and illustrated in the companion document to the original guideline (HIV clinical practice guidelines, New York State Department of Health; 2003), which portrays New York's HIV Guidelines Program. The general implementation strategy is outlined below.

- Statement of purpose and goal to encourage adoption and implementation of guidelines into clinical practice by target audience
- Define target audience (providers, consumers, support service providers).
    - Are there groups within this audience that need to be identified and approached with different strategies (e.g., HIV Specialists, family practitioners, minority providers, professional groups, rural-based providers)?
- Define implementation methods.
    - What are the best methods to reach these specific groups (e.g., performance measurement consumer materials, media, conferences)?
- Determine appropriate implementation processes.
    - What steps need to be taken to make these activities happen?
    - What necessary processes are internal to the organization (e.g., coordination with colleagues, monitoring of activities)?

    - What necessary processes are external to the organization (e.g., meetings with external groups, conferences)?
    - Are there opinion leaders that can be identified from the target audience that can champion the topic and influence opinion?
- Monitor progress.
    - What is the flow of activities associated with the implementation process and which can be tracked to monitor the process?
- Evaluate.
    - Did the processes and strategies work?
    - Were the guidelines implemented?
    - What could be improved in future endeavors?

IMPLEMENTATION TOOLS

Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

New York State Department of Health. HIV prophylaxis following non-occupational exposure including sexual assault. New York (NY): New York State Department of Health; 2004. 42 p. [30 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004

GUIDELINE DEVELOPER(S)

New York State Department of Health - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

New York State Department of Health

GUIDELINE COMMITTEE

Medical Care Criteria Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Chair: Amneris Luque, MD, Associate Professor of Medicine, University of Rochester Medical Center, Rochester, NY, Medical Director, AIDS Center, Strong Memorial Hospital

Committee Vice-Chair: Sheldon Brown, MD, Liaison, Department of Veterans Affairs Medical Center, Associate Professor of Medicine, Mount Sinai School of Medicine, New York, NY, Chief, Infectious Disease Section, Bronx Veteran Affairs Medical Center (111F

Committee Members: Bruce Agins, MD, MPH, Assistant Professor of Medicine, Cornell University Medical College, New York, NY, Medical Director, AIDS Institute, New York State Department of Health; Doug Fish, MD, Head, Division of HIV Medicine, Assistant Professor of Medicine, Albany Medical College; Charles Gonzalez, MD, Assistant Professor of Medicine, New York University School of Medicine, New York, NY, Clinical Investigator, AIDS Clinical Trials Unit, New York University Medical Center - Bellevue Hospital Center; Harold Horowitz, M.D., Professor of Medicine, New York Medical College, Valhalla, NY 10595-1696, Medical Director, AIDS Care Center, Division of Infectious Diseases, Westchester Medical Center; Marc Johnson, M.D., Attending Physician, New York Hospital Queens, Flushing, NY, Assistant Professor of Medicine, Mount Sinai School of Medicine, New York, NY, Medical Director, New York Hospital Queens Primary Care at ACQC; Jessica Justman, MD, Associate Professor of Clinical Medicine, Albert Einstein College of Medicine, Bronx, New York, Associate Director, Center for Infectious Disease Epidemiologic Research, Mailman School of Public Health, Columbia University; Sharon Mannheimer, MD, Assistant Professor of Clinical Medicine, Columbia University College of Physicians and Surgeons, New York, New York, Division of Infectious Diseases, Harlem Hospital Center; Neal Rzepkowski, MD, HIV Care Consultant, New York State Department of Corrections, WENDE HUB, HIV Care Provider, Erie County Medical Center Rural Outreach Clinics, Chautouquez County Department of Health HIV Clinics; Kent Sepkowitz, MD, Memorial Sloan-Kettering Cancer Center; Rona Vail, MD, HIV Clinical Director, Callen-Lorde Community Health Center; Barry Zingman, MD, Medical Director, AIDS Center, Montefiore Medical Center

Liaisons: Barbara Chaffee, MD, MPH; Joseph R. Masci, MD; Noemi Nagy

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- HIV post-exposure prophylaxis following non-occupational exposure including sexual assault. Tables and recommendations. New York (NY): New York State Department of Health; 2004 Jun. 34 p. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.
- HIV clinical practice guidelines. New York (NY): New York State Department of Health; 2003. 36 p. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Print copies: Available from Office of the Medical Director, AIDS Institute, New York State Department of Health, 5 Penn Plaza, New York, NY 10001; Telephone: (212) 268-6108

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on February 2, 2005.

COPYRIGHT STATEMENT

DISCLAIMER

NGC DISCLAIMER

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx.

NGC, AHRQ, and its contractor ECRI make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Date Modified: 10/2/2006